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Request for grant of a patent

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The Patent Office

Cardiff Road

Newport

Gwent NP9 1RH

NEWPORT

1. Your reference

P71654GB1

2. Patent application

0119120.4

1 AUG 2001

3. Name, address and postcode of the or of each applicant (underline all surnames)

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Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

SECTION 30 (1)(b) APPLICATION FILED

8201659001

4. Title of the invention

Leg Ulcer or Wound Vibratory Treatment and Device

See telecon 22/8/01

5. Name of your agent (if you have one)

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Patents ADP number (if you know it)

7914237001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country	Priority application number (if you know it)	Date of filing (day / month / year)
GB	0103893.4	19 Feb 2001

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing (day / month / year)

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 - b) there is an inventor who is not named as an applicant, or
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Patents Form 1/77

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Description	19
Claim(s)	8
Abstract	1
Drawing(s)	15 + 15

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Priority documents

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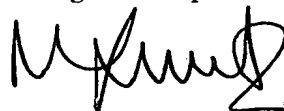
Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents
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11. I/We request the grant of a patent on the basis of this application.

Signature



Date

30 July 2001

12. Name and daytime telephone number of person to contact in the United Kingdom

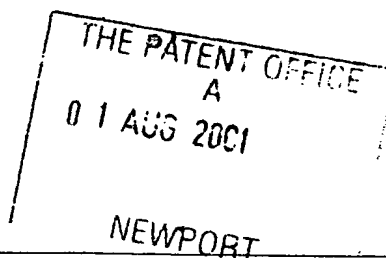
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**Statement of inventorship and of
right to grant of a patent**



The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference

P71654GB1

2. Patent application number
(if you know it)

1 AUG 2001

3. Full name of the or o

0119120.4

Vibro-Pulse Ltd

4. Title of the invention

Leg Ulser or Wound Vibratory
Treatment and Device

5. State how the applicant(s) derived the right
from the inventor(s) to be granted a patent

By Virtue of Contract of
Employment

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7/77 are attached to this form?
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7.

I/We believe that the person(s) named over the page (and on
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0114 274 3701

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Patents ADP number (if you know it):

Reminder

Have you signed the form?

Patents ADP number (if you know it):

Leg Ulcer or Wound Vibratory Treatment and Device

The present invention relates to a vibratory massage device for the treatment of open sore ulcers or other
5 wounds on a human or animal body, and a method of treatment of open sore ulcers or other wounds on a human or animal body.

It is well understood that three-dimensional vibration (referred to as cycloidal vibration) has beneficial effects
10 in improving blood circulation, joint mobility, and respiratory conditions, and relieving tension. Such vibration is in the frequency range of 15 to 75 Hz with an amplitude varying between 0.1 and 0.5 mm, depending on the orthogonal direction.

15 Decubitus ulcers are caused by continuous pressure at specific points of the body when a patient is immobile for extended periods of time. It is known that vibration can assist in preventing the development of such sores and US-A-5606754 suggests a bed which has vibration means to
20 reduce the incidence of bed sores.

Venous ulcers are caused by cracks in dry skin and are notoriously difficult to heal, particularly in elderly patients. The current method of treatment is to cover the affected skin area with a dressing, in order to keep the
25 skin moist and prevent infection from entering the sore, and to immobilise the sore in order to facilitate healing. However, some patients suffer from venous ulcers for extended periods of time in the order of months or even

years before they heal, if ever. There is an evident need for more efficient treatment of ulcers.

US-A-5948009 discloses an ablation electrode for treating canker sore in which vibratory massage is applied to create a lesion. This is said to create the conditions for subsequent healing.

It is an object of the present invention to provide an improved method of treatment of ulcers and wounds.

In accordance with a first aspect of the present invention there is provided a method of treatment of ulcers and wounds of the human or animal body, which method comprises the step of subjecting the body in the area of the ulcer or wound to mechanical vibrations for an effective period of time, said vibrations having a frequency of between 15 and 75 Hz, and an amplitude of between 0.1 and 0.5 mm.

Preferably, said vibrations have components in three orthogonal directions, said frequency being the same or different in each direction, and said amplitude being the same or different in each direction. Preferably said period is more than fifteen minutes, ideally about thirty minutes. The treatment is preferably repeated three times a day.

In another aspect, the present invention provides an ulcer or open wound treatment device comprising:

a drive unit adapted to deliver mechanical vibrations at its surface in three orthogonal directions at a frequency in each orthogonal direction of between 15 and 75 Hz and with an amplitude in each orthogonal direction of between 0.1 and 0.5 mm;

a pad connected to said drive unit; and
pressure applying means by which the pad may be
pressed against the limb of the animal or human.

Preferably, said pressure applying means comprises a
5 strap by means of which the pad may be secured to said
limb.

Preferably, the drive unit is substantially
cylindrical. It may have a casing mounting a motor having
an armature parallel the axis of the cylinder. The motor
10 may drive an eccentrically mounted weight to provide
oscillations of the casing in a radial plane. The motor
may be mounted through flexible mountings in the casing so
that a component of the vibration is created in an axial
direction of the armature.

15 In another aspect, the invention provides the use of a
drive unit and a pad in the manufacture of a device for the
treatment of an ulcer or open wound of a patient, wherein
said drive unit is adapted to deliver mechanical vibrations
at its surface in three orthogonal directions at a
20 frequency in each orthogonal direction of between 15 and 75
Hz and with an amplitude in each orthogonal direction of
between 0.1 and 0.5 mm, and wherein said pad is connected
to said drive unit.

GB-A-2096899 describes a conventional analogue control
25 of a universal AC motor for a vibration device, which
control is found not to provide a smooth delivery of power
to the motor so that, at some frequencies, the three-
dimensional nature of the vibrations is lost.

Preferably, therefore, the motor is electrically powered from mains AC electricity, the drive unit including digital control means to ensure smooth supply of energy to the motor.

- 5 Said digital control means preferably comprises:
- a detector for each zero crossing point of the AC power supply and adapted to disconnect power from the motor when said crossing point is detected;
 - a timer comprising a counter started by said detector;
 - 10 a comparator to compare the count of said counter with a number stored in a memory and to switch power to the motor when said count equals said number.

Preferably, a low voltage transformer is disposed between the power supply and detector. A rectifier may
15 convert the power supply to the motor to DC, if the motor is a DC motor.

Preferably said number is adjustable to vary the power supplied to the motor, and hence its speed of rotation and hence said frequency.

- 20 Preferably said counter is capable of providing about 250 counts in each half cycle of the power supply.

Preferably the drive unit operates at a frequency of between 30 and 60 Hz.

- 25 When the method above employs the device provided by the present invention, the device may be applied to the leg of a patient suffering venous ulcers by said pressure applying means and so that, in use, the device delivers vibrations in the leg of the patient at a frequency of

between 20 and 50 Hz, and with an RMS acceleration in the axial direction of the tibial bone of between 5 and 15 ms^{-2} , and in a radial plane with respect to the tibial bone with an RMS acceleration of between 2 and 5 ms^{-2} .

5 Preferably, the device delivers vibrations in the leg of the patient at a frequency of about 30 Hz, and with an RMS acceleration, in the axial direction of the tibial bone, of about 10 ms^{-2} , and, in a radial plane with respect to the tibial bone, with an RMS acceleration of between 2
10 and 5 ms^{-2} .

 Despite the apparent contrary indication that movement will unsettle the healing of wounds, and particularly venous ulcers, it has been surprisingly discovered that cycloid vibrations have a beneficial effect on their
15 healing. Without being reliant on any particular theory, this beneficial effect may be due to improved blood circulation caused by the vibrations and increased moisture in the upper dermis and epidermis. Indeed, the healing effects of the present invention are especially felt when
20 two optional features of the invention are fully exploited. The first is the three-dimensional aspects of the vibration; some benefit is experienced with two-dimensional vibration but significantly enhanced effects have been noted with three-dimensional vibrations, particularly when
25 employing the motor control described above which provides smooth power delivery to the motor. The second is the pressure applying means, which serves to unite the patient's limb with the device and ensures deep transmission of the vibrations into the flesh of the
30 patient.

Furthermore, the invention also provides a device as described above further comprising a detachable cover for the pad and drive unit. Said cover may comprise an open pouch to receive said pad and drive unit, fastening means
5 to close the pouch about the pad and drive unit, openings in the cover being provided to permit cooling airflow into the drive unit.

Said cover preferably comprises a deep pouch to receive the pad, and a flap on a front side of the pouch
10 extending from the lip thereof and having a first fastener along its edge remote from said front lip and adapted to detachably fasten to a second fastener along the lip of the pouch on its rear side, two of said openings thereby being defined between each free edge of the flap and the lip of
15 the pouch between its front and rear sides respectively.

Preferably, one of said fasteners comprises a strip of hooked material while the other comprises a strip of hooped material, so that pressing said materials together effects a releasable connection.

20 Preferably, the cover is of impervious material to prevent liquid from penetrating and contaminating a pad received within the cover.

Preferably, a strap is integrally formed in the cover. Indeed, there may be two straps spaced along the pouch so
25 that, if one is in the area of the ulcer or wound of the patient when the patient's limb is located appropriately with respect to the pad, it can be left undone. When the other strap is secured, this applies sufficient pressure to provide the improved vibration transmission.

Preferably, the or each strap is sewn at one end into a side edge of the pouch and at its other end is provided with a third fastener, the other side edge of the pouch being provided with a complimentary fourth fastener.

5 Preferably, the fourth fastener extends along the length of the pouch to vary the possible disposition of the or each strap when the third and fourth fasteners are engaged.

10 The third and fourth fasteners may comprise hooped and hooked fabric material. Indeed, the fourth fastener may comprises a strip of such material along a significant part of the length of the side edge of the pouch so that the or each strap can vary in its position of attachment to the other side of the cover.

15 The cover serves to protect the pad from contamination from weeping wounds and ulcers. Such weeping tends to occur when they are treated in accordance with the present invention.

20 In another aspect, the cover may comprise a simple sheet of material having means to gather its edges on an underside of the pad of the vibratory device, and render the sheet taught on an operative side of the pad against which a patient's limb is intended to lie. At least one hole is preferably provided in the sheet to permit the
25 drive unit to protrude through.

The cover may comprise means to fasten a strap to the cover, and hence to the pad, for the purpose of providing said pressure applying means. Said strap fastening means may comprise strips of hooked or hooped material along the

sides of the cover to which a strap of respectively hooped or hooked material may be fastened.

Indeed, in another aspect, the invention provides a cover for a vibratory massage device as defined herein, the
5 cover being as defined above.

Furthermore, the invention provides a kit of parts, comprising a cover and a strap, and in its simplest form this may comprise a simple sheet suitable for protecting the pad; and a strap suitable for applying the requisite
10 pressure when securing a patient's limb to the pad.

The invention is further described hereinafter, by way of example, with reference to the accompanying drawings, in which:-

Figure 1 is a perspective view of a vibratory massage
15 device in accordance with the present invention, (having attached thereto a transducer pack analysing the vibrations of the pad in three orthogonal directions x, y and z);

Figure 2 is an assembly drawing of a drive unit and frame of the device of Figure 1;

20 Figure 3 is a side view of the device of Figure 1 strapped to a patient's leg with the drive unit at the heel of the patient;

Figure 4 is a similar view to Figure 3, but with the drive unit under the knee of the patient;

25 Figure 5 is a perspective view of the device of Figure 1, with the casing open;

Figure 6 is a top view of the drive unit with the casing open;

Figure 7 is a schematic representation of the control
30 function of the motor of the drive unit;

Figures 8 a to j are graphs of RMS acceleration of the vibrations produced under varying conditions in the three orthogonal directions x, y and z, as well as the frequency of the vibrations;

5 Figures 9a and b are respectively graphs of acceleration in each direction plotted against time, and a frequency range plot in each direction, both at a preferred speed of operation;

10 Figures 10a and b are as Figure 9, but at a higher speed;

Figures 11a, b and c show the frequency of operation for different conditions of operation against speed setting of the device;

15 Figures 12a, b and c show a cover in accordance with the present invention: in perspective view; in perspective view again but with a device inside; and in plan as a blank before assembly; and

Figure 13 shows in perspective another form of cover within the ambit of the present invention.

20 In the drawings, a vibratory massage device 10 in accordance with the present invention comprises a drive unit 12. The drive unit comprises a casing 14 housing an electric low voltage DC motor 16 mounted in the casing through flexible mountings 18,20. The motor drives an
25 eccentric weight 22 mounted on a fan 23 on each end of an armature 24. On rotation of the armature 24 motor 16 imparts a vibration in the casing 14 in a radial plane (x,y) with respect to the armature 24. Because the mountings 18,20 are soft, a component of the vibration
30 occurs in a direction orthogonal (z) to the radial plane.

Consequently, the vibration of the casing in response to the vibration of the motor is three-dimensional.

To the casing is fixed, by screws 29 (see Figure 6) retained in apertures 25 of the casing, a frame 27. On the frame is disposed fabric cushioning to form a pad 110. The cushioning covers the drive unit 12 with a sleeve 40..

The motor is adapted to rotate at about 2400 rpm providing a frequency of vibration of about 40 Hz. Depending on various factors (primarily connected with the degree of restraint placed upon the device by its location on the limb of an animal) the amplitude of vibration in each direction may be different and between about 0.1 mm and 0.5 mm.

However, a speed control arrangement 90 is provided (see Figure 7), conveniently disposed in a separate hand unit (not shown). Arrangement 90 controls the power supplied to the motor, and is connected to AC mains voltage 92, which typically is between 50-60 Hz. The mains supply is connected to a double bobbin isolation transformer T having a nominal 24volt AC output. That supply is fed to a switch/rectifier 94, which in turn provides power to the motor 16 along cable 32.

However, a detector 96 detects the output of the transformer T and activates the switch 94 to commence supply of current to the motor 16 when the voltage is zero; that is to say, at each zero crossing of the supply voltage.

At the same time, the detector 96 activates a timer 98 to commence counting, the output of which counter is

supplied to a comparator 100. The comparator 100 is also supplied with the value of a number stored in a memory 102 and, when the count of the counter 98 reaches the number stored in the memory 102, the comparator activates the switch 94 to interrupt supply of current to the motor 16.

The memory is provided with means 104 by which the number stored can be changed, so that the speed of the motor can be varied. Conveniently, it is found that the counter should count at a rate of about 25 KHz giving about 250 steps in each half cycle.

Because the frame 27 is rigidly fixed to the casing 14 of the drive unit 12, vibrations of the drive unit 12 are therefore transmitted to the pad 110. The pad is about 400 mm long and about 250 mm wide at the motor end and about 200 mm wide at its other end.

In use, a patient suffering from a leg ulcer lays the affected leg 29 longitudinally along the pad. Whether the motor is at the heel end 31 of the leg, as shown in Figure 3, or is under the knee 33, as shown in Figure 4, is a matter of patient choice. However, if an ulcer is on the patient's ankle or lower leg, the former arrangement may be preferable, whereas if it is on the calf or higher, the latter arrangement may provide more direct delivery of vibrations to the site and environment of the ulcer.

Pressure applying means in the form of a strap 46 is employed to press the leg into close contact with the pad 110, although any means will do, such as a weight. The strap 46 conveniently is separate from the pad and comprises a band of material having hooped nylon on one

surface and hooked nylon on the other. When its ends are overlapped and pressed together after wrapping around the patient's leg and pad, the strap secures the pad to the patient's leg. The strap is about 100 mm wide.

5 In any event, Table 1 shows the results of preliminary trials conducted on patients suffering long term problems with ulcers. In each case, the patient arranged a device
10 in accordance with the present invention as shown in Figures 3 or 4 with a strap 46 comfortably, but firmly, pressing the pad 110 against the patient's leg.

The motor control was switched to setting 5 and vibration was effected for about thirty minutes 3 times per day. The results of these treatments are shown in Table I below.

15 In each case the conventional treatment regime was maintained, along side the vibration treatment. This comprised keeping wounds dressed with two-layer pressure bandages to reduce the potential for infection. Dressings
20 were changed bi-weekly, unless no suppuration or weeping was evident, in which case only weekly change of dressings were effected.

Patient Age and Sex	Age of Ulcer Weeks	Position of Ulcer	Vibration treatment (Weeks)	Reduced Swelling Y/N	Pain Reduction Start/End	Improved Mobility Y/N	Condition of Ulcer after treatment
84M	100	Ankle	9	Y **	0/0		Reduced Size
84F	6	Above ankle	6	Y	2/0.5 (no pain at nights)		Scab in 3 weeks, healed in 6 weeks
73M	17	Ankle	10	Y	2/less		60% healed
85F	39	Above ankle	10	N	5/1		Reducing slowly
86F	17	Above ankle	5	Y	1/0 week 4 @		HEALED
73M	17	Small ulcers	5	N	1/0 week 2 @		HEALED
54M	75	Ankle	2	Y (after 4 days)	0/0		Improvement after 4 days
73M	200	Ankle	2	Y	2.5/1.5		Improving
90M	50	Ankle	2	Minimal	3.5/2.5		Healing

Table I

* Pain is on scale 0 to 5 where 0 is no pain and 5 is intense pain

** Temporary increase in swelling at week 5 but reduced overall

As can be seen from Table I above, the response of patients, even those afflicted with long term ulcers that had hitherto failed to respond to conventional methods of treatment, was in all cases favourable with healing to a greater or lesser extent being effected in each case.

Turning now to Figures 8 to 11, these illustrate graphically the vibration regime established by the pad under the conditions shown in Table II below.

Condition	Subject	Motor at	Support	Strap	Measured at
1	A	Knee	Free	Tight	Middle
2	A	Knee	Firm	Tight	Middle
2A	A	Knee	Soft	Tight	Middle
3	A	Knee	Soft	Tight	Motor end
4	A	Knee	Soft	Loose	Middle
5	A	Heel	Soft	Tight	Middle
6	A	Heel	Soft	Tight	Other end
7	A	Heel	Firm	Tight	Middle
8	B	Heel	Firm	Tight	Middle
9	B	Heel	Soft	Tight	Middle

Table II

The same subject person (A) was used in most tests. The position of the motor was varied between under the "Knee" (Figure 4 arrangement) or at the "Heel" (Figure 3

arrangement). The leg with the pad attached was either "Free" (not shown), supported on a "Firm" base, or supported on a "Soft" cushion 37. The strap 46 was either "Tight" or, in one case, "Loose". Measurements of
5 accelerations were made using accelerometer transducers positioned to measure in each of the three axes x, y and z. The transducers (not shown) were disposed on a base 35 (see Figure 1) between the pad 110 and the subject's leg 29. The base was either in the "Middle" of the pad, at the
10 "Motor end" thereof, or it's "Other end". The use of quotation marks is merely a reference to the same terms used in Table II above.

Referring first to Figures 11a, b and c, in most conditions, the frequency of operation was consistently
15 proportional to speed setting. However, when a particularly rigid connection is achieved (see conditions 7 and 8 where the motor was under the heel of the subject, there was firm support, and a tight strap), the subject's leg will have absorbed substantial energy from the device.
20 This results in a reduction in the increase of speed and frequency with increasing speed setting.

Referring to Figures 8a to j, it can be seen that, with increasing speed, the acceleration in the x direction, which is in the longitudinal direction with respect to the
25 subjects leg, increases exponentially. On the other hand, in the y and z directions, the increase is more proportional and in some cases not especially apparent. It is suspected that for this reason is it found in practice that speed setting 5 appears to be the optimal treatment
30 speed. Indeed, in some conditions, the z component of

acceleration almost disappears at higher speeds, leaving essentially just one dimension (x) to the vibration, with a minor component in the y direction.

However, at speed setting 5 or thereabouts, the vibration is quite evenly three dimensional.

In Figures 9a, the actual acceleration in each direction is plotted against time so that, for example, over about 0.1 seconds 2.5 acceleration cycles occur. This equates to a frequency of about 25 Hz, the amplitude of the accelerations being greatest in the x direction and least in the z direction. In Figure 9, the speed setting is 4.5, whereas in Figure 10 it is 9.5, so that about six acceleration cycles of substantially greater amplitude occur in the measurement period. This equates with a frequency of about 60 Hz.

In both Figures 9b and 10b, the frequency range is plotted against the acceleration at each frequency and it can be seen that there is only one spike of any significance in each direction at both speed levels.

Turning to Figures 12a, b and c, a cover 150 is illustrated comprising a pouch 152 of an impervious material such as plastics or nylon. In the context of the present invention, "impervious" should be understood to mean that liquid weeping from a bandaged wound or ulcer of a patient undergoing treatment with the device will not, on the whole, penetrate the material and contaminate the pad. However, for the purposes of patient comfort, the cover may not be utterly impervious and therefore on occasions some contamination could occur if significant leakage occurs.

The pouch has a front 154 and a back 156, and two sides 158, 160. The pouch 152 has a top lip 162 and, on the rear side 156 of the pouch a flap 164 depends from the lip 162.

5 At the end of the flap is a strip 166 of hooped nylon material. On the front face 154 of the pouch, near the lip 162, is a strip of hooked nylon 168.

The pouch 154 is shaped to snugly receive the pad 110 of a massage device 10 of the type shown in Figures 1 to 6.
10 The motor 12 is not received in the pouch 154. Instead, the flap 164 covers the motor when the flap is folded over and the first and second fasteners formed by the strips 166, 168 are inter-engaged. Thereupon, the flap defines, with the lip 162 at the sides 158, 160, two openings 170,
15 172 through which the ends of the drive unit 12 project. The drive unit 12 has cooling slots 174 through which air is drawn to cool the motor 16 by the fans 23. This flow is therefore not impeded by the cover 152.

The cover 150 has two straps 46a, b sewn into the join
20 155 between the front rear faces 154, 156 (indeed, the pouch is conveniently formed by sewing a blank as shown in Figure 12c along edges 155a, b after folding along line 157 forming the bottom end of the pouch). The straps 46a, b have strips 176 of hooped nylon at their ends. On the
25 other side 160 of the pouch is provided a long strip 178 of hooked nylon. The strips 176, 178 form third and fourth fasteners and when a patient's leg is placed along the pad 110 (front face 154 of cover 150) the leg can be pressed against the device 10 by folding over the straps 46a, b and
30 engaging the fasteners 176, 178.

Should either strap tend to apply pressure to a wound or ulcer on the patient's leg, the elongate strip 178 permits longitudinal adjustment of the attachment of the straps. Indeed, one strap could be omitted altogether
5 without detracting from the benefits of the invention.

The strips 176 are somewhat elongate in order to accommodate different dimensions of different patient's legs.

Finally, Figure 13 illustrates an alternative
10 embodiment of a cover within the ambit of the present invention. Any cover that serves the purpose of protecting the pad from contamination has its place, but Figures 12 and 13 illustrate novel covers. Cover 150' comprises a simple sheet 182 of material that is impervious to liquid
15 weeping from wounds or ulcers. The sheet has a hem 180 incorporating a tie string (not shown) which can gather the edges of the sheet on the underside 110b of the pad 110. The cover is drawn taught over the top, that is to say, operative, side 110a of the pad 110. Alternative
20 tightening arrangements are quite feasible, for example, several draw strings could be provided at the corners and sides of the sheet 150' to be tied together across underside 110b of the pad 110.

In any event, a strap 46c could be integrated with the
25 cover 150', as described above with reference to Figure 12, or be separate, as shown in Figure 13. In this case, two strips 178a,b of hooked material are provided along the sides of the sheet 150, while the strap 46c either comprises, or is covered with, hooped material. Then, when
30 the cover is on the pad, and a patient's limb is resting on

the top side 110a of the pad 100, the strap 46c can be applied anywhere along the length of strip 178a (for example) of the cover 150', passed over the patient's limb and fastened to the strip 178b. The possibility of
5 variation of the positioning of the strap with respect to the patient's limb is an important comfort feature.

CLAIMS

1. An ulcer or open wound treatment device comprising:

5 a drive unit adapted to deliver mechanical vibrations at its surface in three orthogonal directions at a frequency in each orthogonal direction of between 15 and 75 Hz and with an amplitude in each orthogonal direction of between 0.1 and 0.5 mm;

a pad connected to said drive unit; and

10 pressure applying means by which the pad may be pressed against the limb of the animal or human.

2. A device as claimed in claim 1, in which said pressure applying means comprises a strap by means of which the pad may be secured to said limb.

15 3. A device as claimed in claim 1 or 2, in which said drive unit is substantially cylindrical.

4. A device as claimed in claim 3, in which the drive unit comprises a casing mounting a motor having an armature parallel the axis of the cylinder.

20 5. A device as claimed in claim 4, in which said motor drives an eccentrically mounted weight to provide oscillations of the casing in a radial plane.

6. A device as claimed in claim 5, in which said motor is mounted through flexible mountings in the casing
25 so that a component of the radial oscillations is created in an axial direction of the armature.

7. A device as claimed in claim 4, 5 or 6, in which the motor is electrically powered from mains AC electricity, the drive unit including digital control means to ensure smooth supply of energy to the motor.

5 8. A device as claimed in claim 7, in which said digital control means comprises:

a detector for each zero crossing point of the AC power supply and adapted to disconnect power from the motor when said crossing point is detected;

10 a timer comprising a counter started by said detector;
a comparator to compare the count of said counter with a number stored in a memory and to switch power to the motor when said count equals said number.

15 9. A device as claimed in claim 8, in which a low voltage transformer is disposed between the power supply and detector.

10. A device as claimed in claim 9, in which a rectifier converts the power supply to the motor to DC and the motor is a DC motor.

20 11. A device as claimed in claim 8, 9 or 10, in which said number is adjustable to vary the power supplied to the motor, and hence its speed of rotation and hence said frequency.

25 12. A device as claimed in any of claims 8 to 11, in which said counter is capable of providing about 250 counts in each half cycle of the power supply.

13. A device as claimed in any preceding claim, in which said pad comprises a frame rigidly fixed to the drive unit to transmit vibrations into the pad.

14. A device as claimed in any preceding claim, in which said pad is elongate, of length between 300 and 500 mm and width between 100 and 200 mm, said drive unit being mounted at one end of said pad.

15. A device as claimed in claim 14, in which the pad tapers from the end at which the drive unit is disposed.

16. A device as claimed in claim 14 or 15, when dependent on claim 2, in which the strap is disposed about half way along the length of the pad.

17. A device as claimed in any preceding claim, in which the drive unit operates at a frequency of between 30 and 60 Hz.

18. A device as claimed in any preceding claim, further comprising a cover.

19. A device as claimed in claim 18, in which said cover is in the form of an open pouch to receive said pad and drive unit, and fastening means to close the pouch about the pad and drive unit, at least one opening in the cover being provided to permit cooling airflow into the drive unit.

20. A device as claim in claim 19, in which said cover comprises a deep pouch to receive the pad and a flap on a front side of the pouch extending from the lip thereof and having a first fastener along its edge remote from said

front lip and adapted to detachably fasten to a second fastener along the lip of the pouch on its rear side, two of said openings thereby being defined between each free edge of the flap and the lip of the pouch between its front and rear sides respectively.

21. A device as claimed in claim 20, in which one of said fasteners comprises a strip of hooked material while the other comprises a strip of hooped material, so that pressing said materials together effects a releasable connection.

22. A device as claimed in claim 18, in which the cover comprises a sheet of material having means to gather its edges on an underside of the pad, and render the sheet taught on an operative side of the pad against which a patient's limb is intended to lie.

23. A device as claimed in claim 22, when dependent on claim 2, in which the cover comprises means to fasten the strap to the cover, and hence to the pad, for the purpose of providing said pressure applying means.

24. A device as claimed in claim 23, in which said strap fastening means comprises strips of hooked or hooped material along the sides of the cover to which the strap, comprising respectively hooped or hooked material, may be fastened.

25. A device as claimed in claim 22, 23 or 24, in which at least one hole is provided in the sheet to permit the drive unit to protrude therethrough.

26. A device as claimed in any of claims 18 to 23 when dependent on claim 2, in which said strap is integrally formed with the cover.

27. A device as claimed in claim 26, in which there are two straps spaced along the cover.

28. A device as claimed in claim 26 or 27, in which the or each strap is connected at one end to a side edge of the cover and at its other end is provided with a third fastener, the other side edge of the cover being provided with a complimentary fourth fastener.

29. A device as claimed in claim 28, in which the fourth fastener extends along the length of the cover to vary the possible disposition of the or each strap when the third and fourth fasteners are engaged.

30. A device as claimed in claim 28 or 29, in which the third and fourth fasteners comprise hooped and hooked fabric materials.

31. A device as claimed in claims 29 and 30, in which the fourth fastener comprises a strip of such material along a significant part of the length of the side edge of the cover so that the or each strap can vary in its position of attachment to the other side of the cover.

32. A device as claimed in any of claims 18 to 30, in which the cover is of impervious material to prevent liquid from penetrating and contaminating a pad received within the cover.

33. A method of treatment of ulcers and wounds of the human or animal body, which method comprises the step of subjecting the body in the area of the ulcer or wound to mechanical vibrations for an effective period of time, said
5 vibrations having a frequency of between 15 and 75 Hz, and an amplitude of between 0.1 and 0.5 mm.

34. The method of claim 33, in which said vibrations have components in three orthogonal directions, said frequency being the same or different in each direction,
10 and said amplitude being the same or different in each direction.

35. The method of claim 33 or 34, in which said period is more than fifteen minutes, ideally about thirty minutes.

15 36. The method of claim 33, 34 or 35, in which the treatment is repeated three times a day.

37. The method of any of claims 33 to 36, employing a device as claimed in any of claims 1 to 32.

20 38. The method of claim 37, in which the device is applied to the leg of a patient suffering venous ulcers by said pressure applying means and so that, in use, the device delivers vibrations in the leg of the patient at a frequency of between 20 and 50 Hz, and with an RMS acceleration in the axial direction of the tibial bone of
25 between 5 and 15 ms^{-2} , and in a radial plane with respect to the tibial bone with an RMS acceleration of between 2 and 5 ms^{-2} .

39. The method of claim 38, in which the device delivers vibrations in the leg of the patient at a frequency of about 30 Hz, and with an RMS acceleration in the axial direction of the tibial bone of about 10 ms^{-2} , and
5 in a radial plane with respect to the tibial bone with an RMS acceleration of between 2 and 5 ms^{-2} .

40. A cover for a vibratory massage device as claimed in any of claims 1 to 17, said cover comprising an open-pouch to receive said pad and drive unit, fastening means
10 to close the pouch about the pad and drive unit, at least one opening in the cover being provided to permit cooling airflow into the drive unit.

41. A cover as claimed in claim 40 having the features as defined in any of claims 20 or 21, or claims 26
15 to 32 when dependent on claims 20 or 21.

42. A cover for a vibratory massage device as claimed in any of claims 1 to 17, said cover comprising a sheet of material having means to gather its edges on an underside of the pad when disposed thereon, and render the sheet
20 taught on an operative side of the pad against which a patient's limb is intended to lie, the cover further comprising means to fasten a strap to the cover, and by means of which pressure can be applied between the patient's limb and the pad covered by said cover.

25 43. A cover as claimed in claim 42 having the features as defined in any of claims 24 or 25, or claims 26 to 32 when dependent on claims 24 or 25.

44. Use of a drive unit and a pad in the manufacture of a device for the treatment of an ulcer or open wound of

a patient, wherein said drive unit is adapted to deliver mechanical vibrations at its surface in three orthogonal directions at a frequency in each orthogonal direction of between 15 and 75 Hz and with an amplitude in each
5 orthogonal direction of between 0.1 and 0.5 mm, and wherein said pad is connected to said drive unit.

45. Use as claimed in claim 44 having the features of any of claims 2 to 32.

46. A kit of parts comprising a cover suitable for
10 covering a device as claimed in any of claims 1 to 17, and a strap suitable for applying pressure between the pad of the device and a patient's leg.

47. An ulcer or open wound treatment device, or a cover therefor, substantially as hereinbefore described
15 with reference to the accompanying drawings.

48. A method of treatment of ulcers and wounds of the human or animal body, substantially as hereinbefore described with reference to the accompanying drawings.

Abstract - 0119120.4

Abstract title

Ulcer or Wound vibratory treatment device

Abstract

A ulcer or open wound treatment device 10 comprising a drive unit 12 delivers mechanical vibrations at its surface in three orthogonal directions at a frequency in each direction of 15-75 Hz and with an amplitude in each direction of 0.1-0.5 mm, a pad 110 connected to the drive unit 12, and a pressure application means by which the pad 110 may be pressed against the animal or patient's limb.

In another embodiment a cover for a vibratory device comprises an open pouch, fastening means and an opening to allow cooling of the drive unit 12.

In a further embodiment a cover for a vibratory device comprises a material sheet gathered at its edges further comprising means to fasten a strap 46 to the cover.

Another embodiment comprises a kit of parts including a cover for covering the vibratory device and a strap 46 for applying pressure between the pad 110 and a patient's leg.

[Fig 2]

ABSTRACT

Leg Ulcer or Wound Vibratory Treatment and Device

5 An ulcer or open wound treatment device (10) comprises
a drive unit (12) adapted to deliver mechanical vibrations
at its surface in three orthogonal directions at a
frequency in each orthogonal direction of between 15 and 75
Hz and with an amplitude in each orthogonal direction of
10 between 0.1 and 0.5 mm.

A pad (110) is connected to the drive unit, and a
strap (46) enables the pad to be pressed against the limb
of the animal or human.

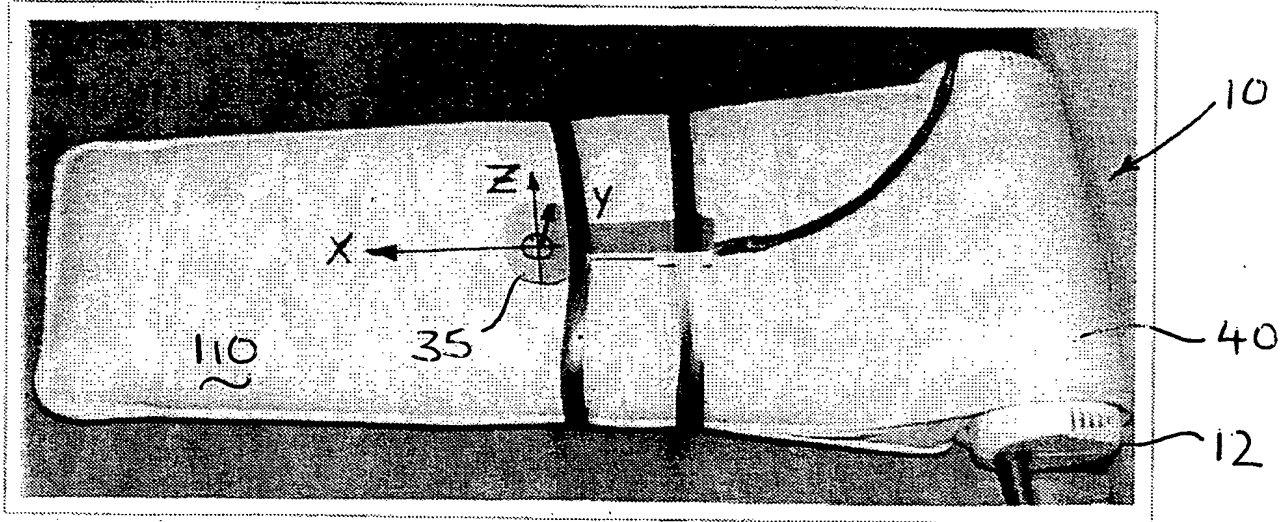
15 The motor drives an eccentrically mounted weight (22)
to provide oscillations of the casing in a radial plane.

The device is employed to treat a patient suffering
from leg ulcers and other wounds by applying three-
dimensional vibrations.

20 A cover (150) is provided to protect the pad (110)
from contamination.

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Photograph 2: Transducer on Cyclopad



Photograph 4: Basic arrangement, motor at heel, soft support

Figure 1

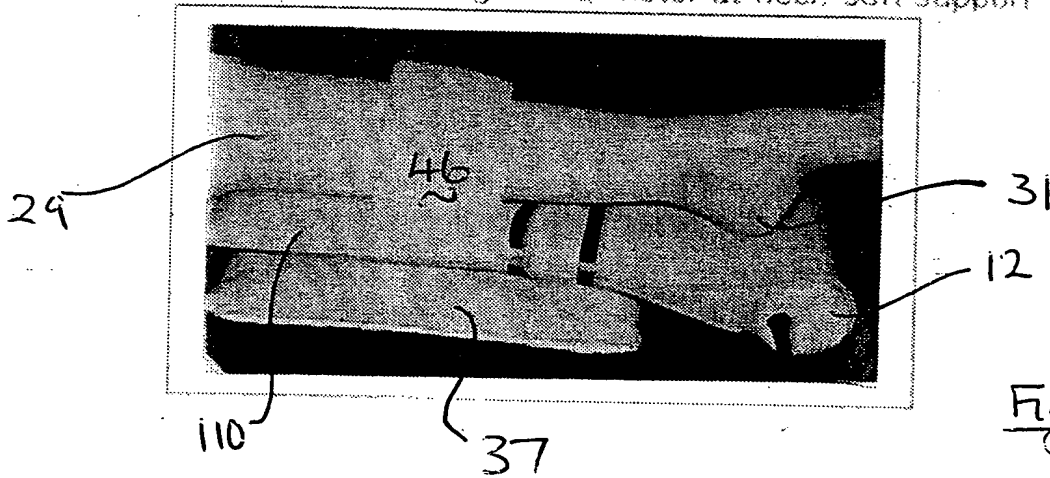


Figure 3

Photograph 5: Alternative arrangement, motor at knee

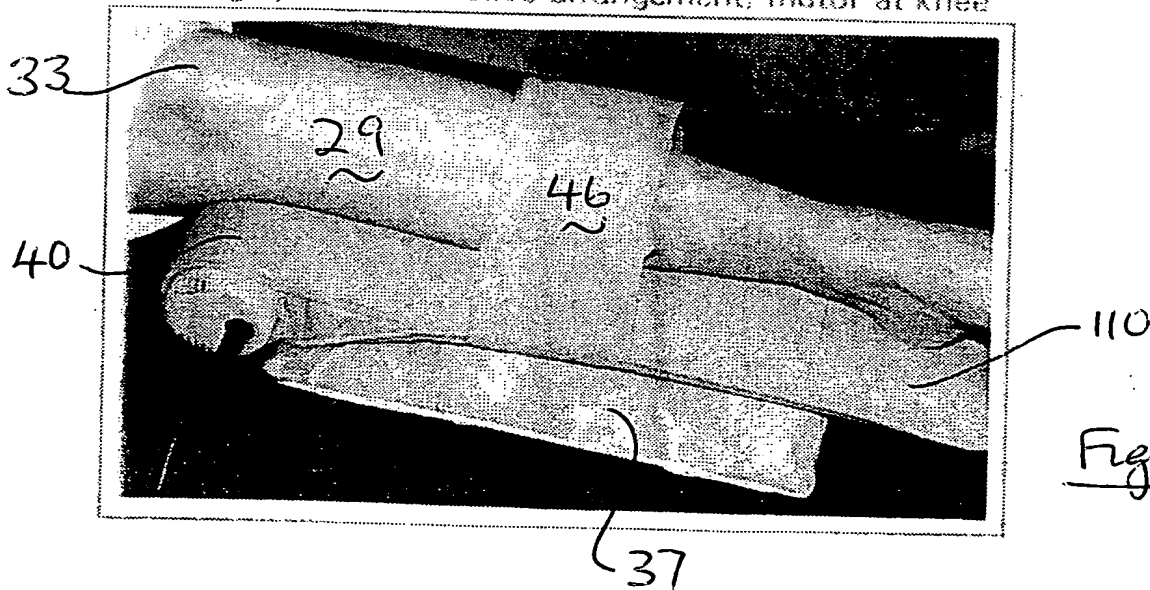
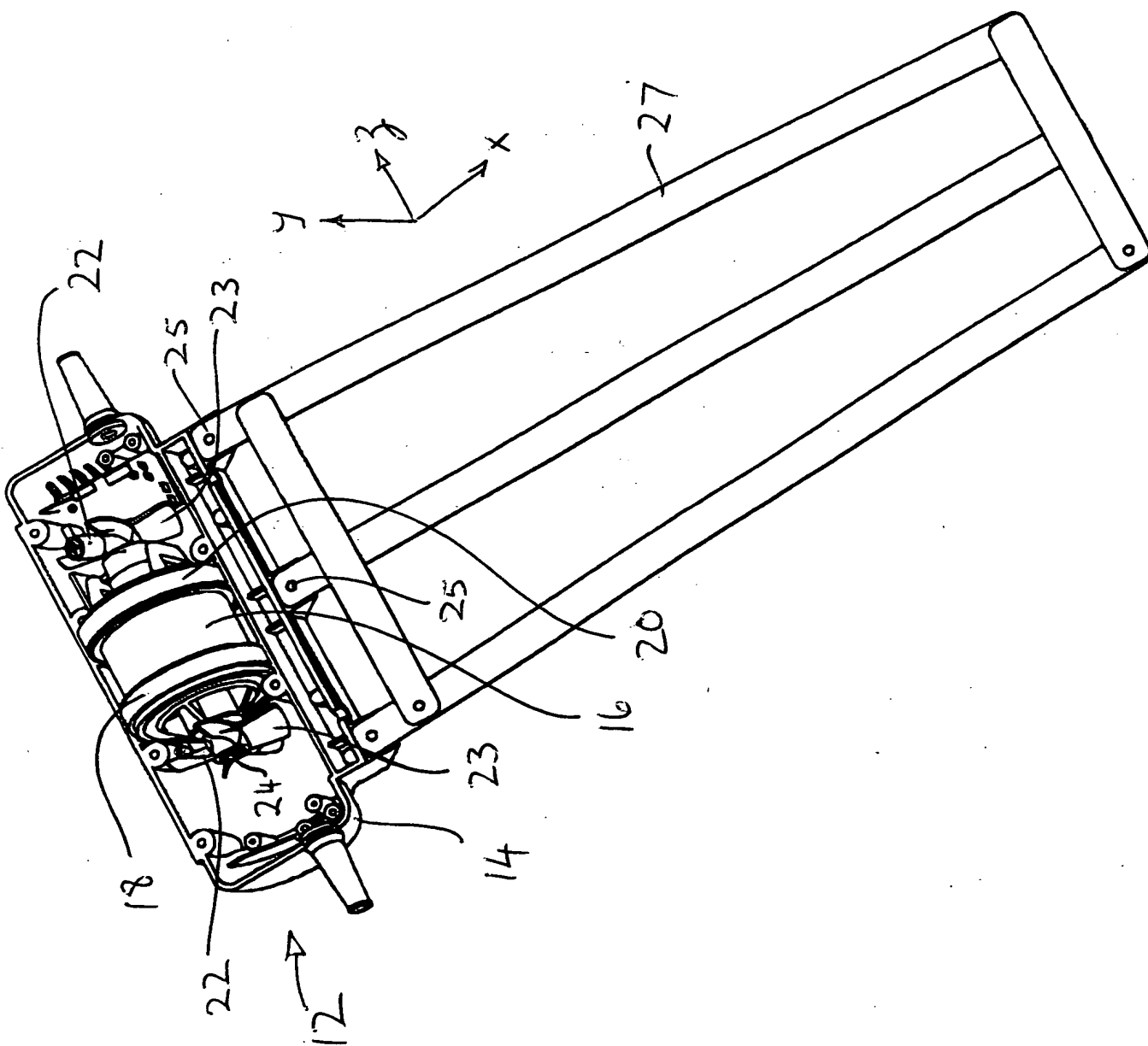


Figure 4

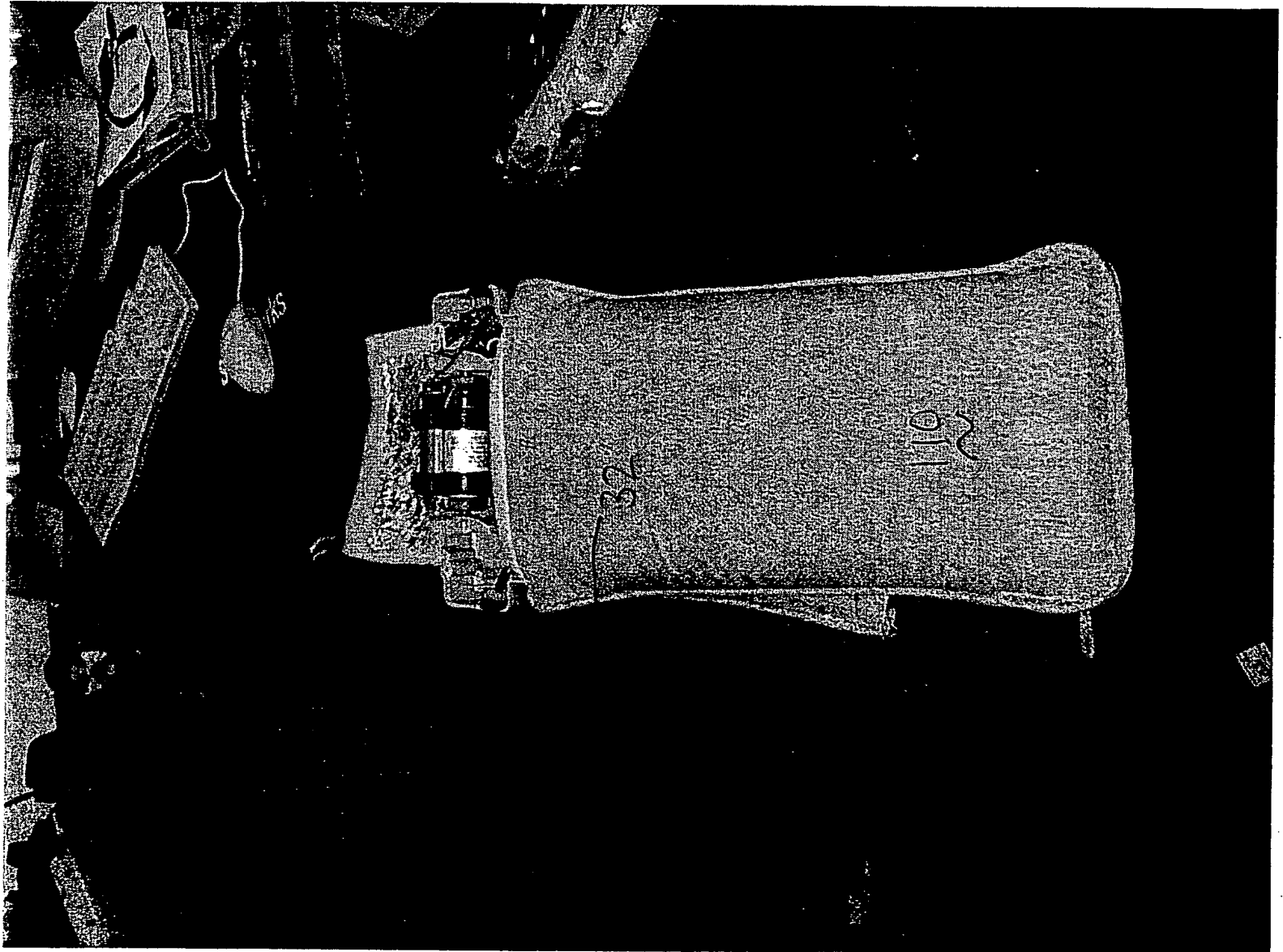
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Figure 2



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Figure 5



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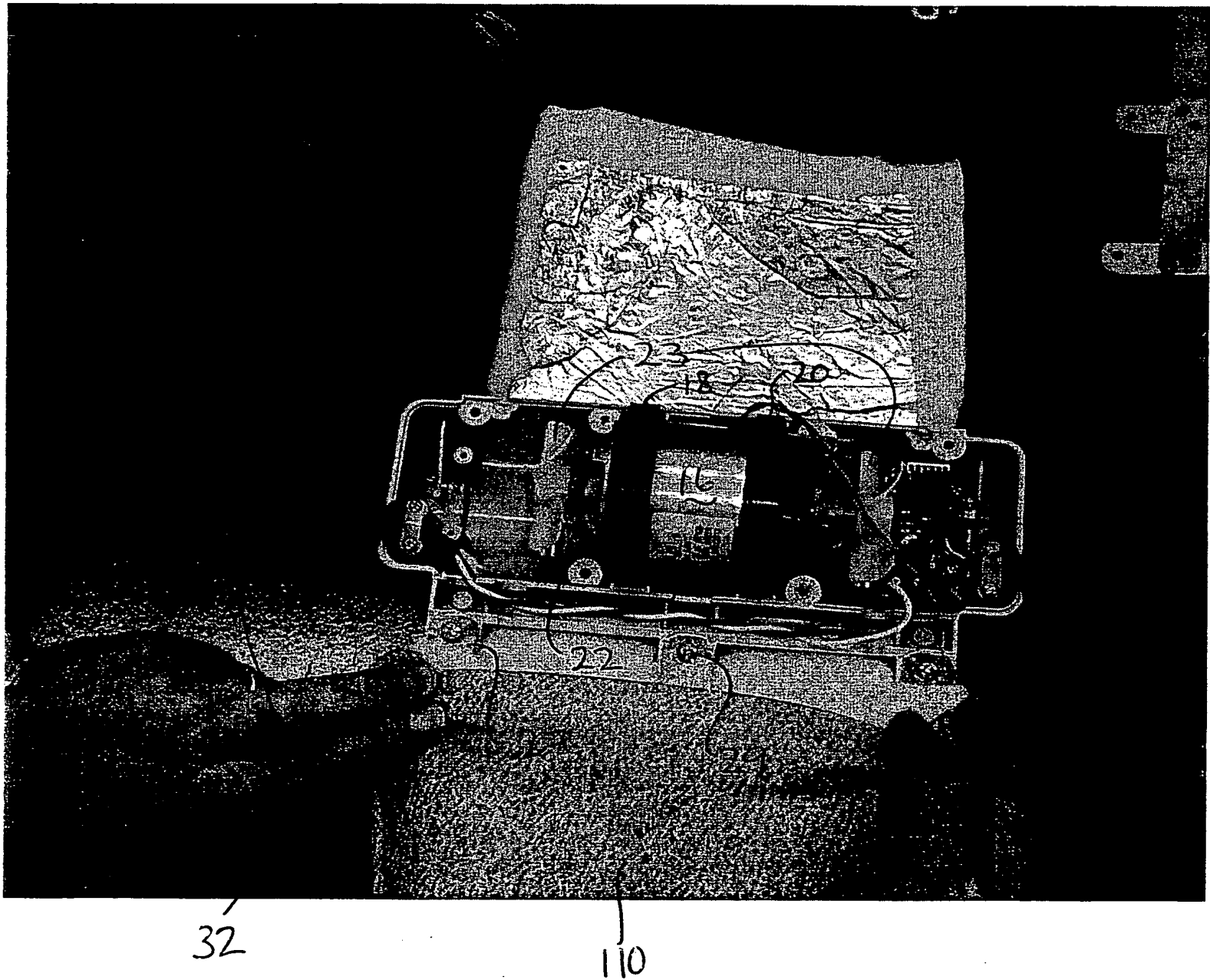
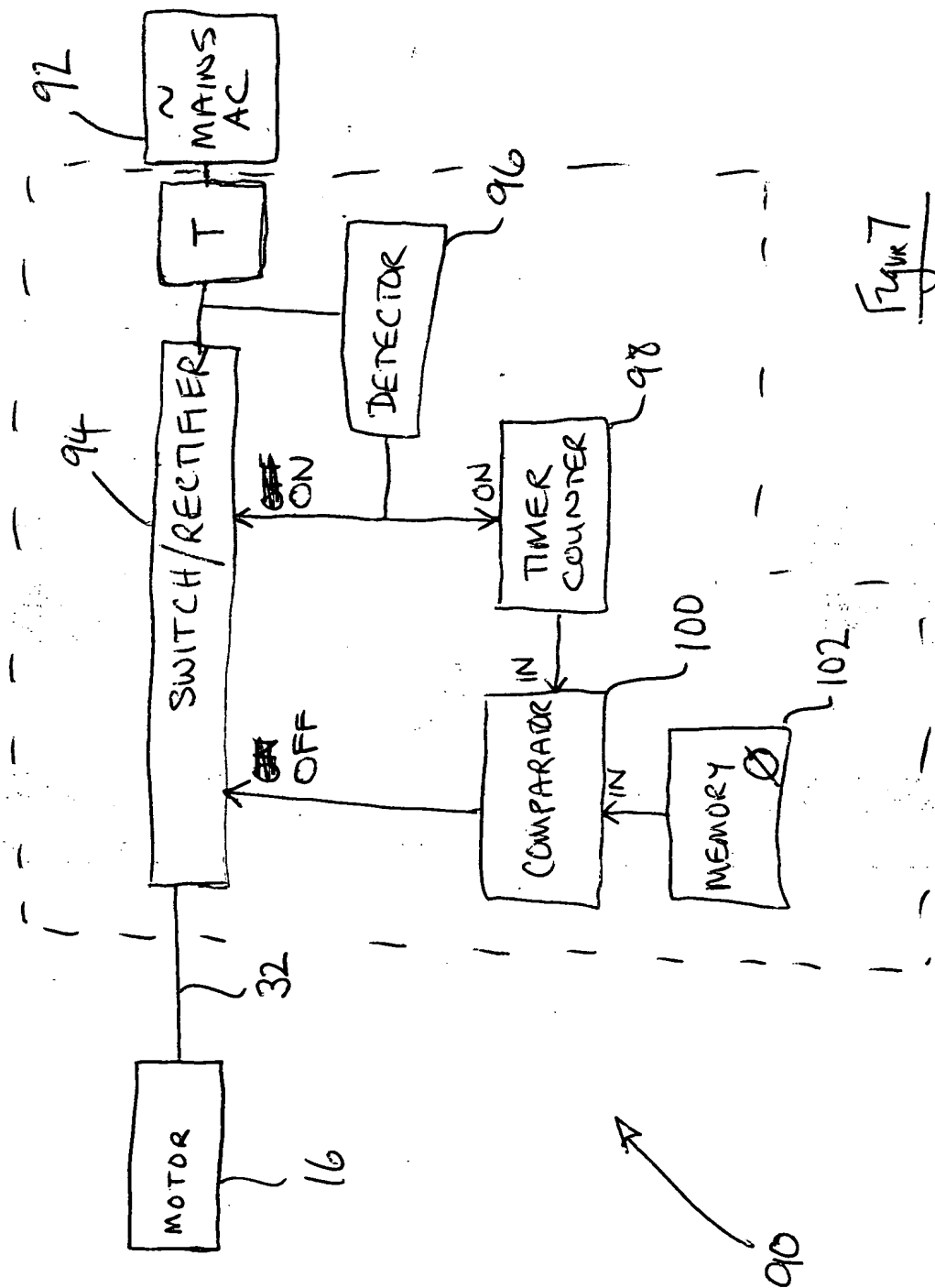


Figure 6

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~~2. Cyclical tests~~ ~~Magnitude results~~

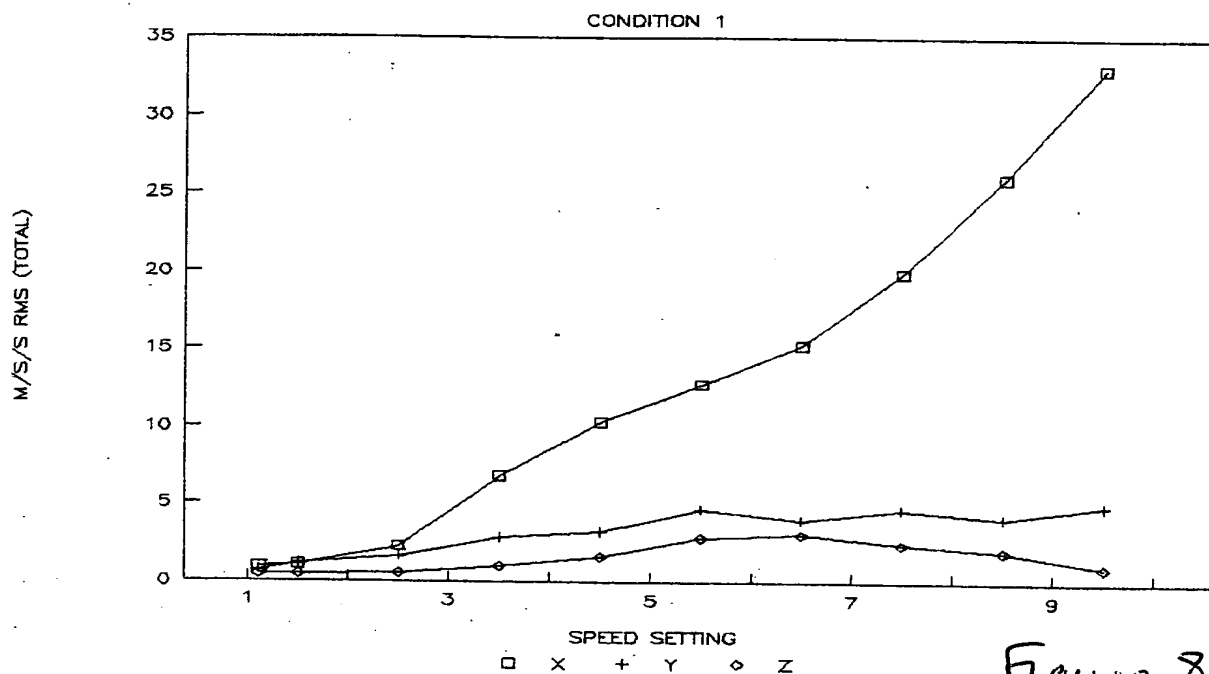


Figure 8a

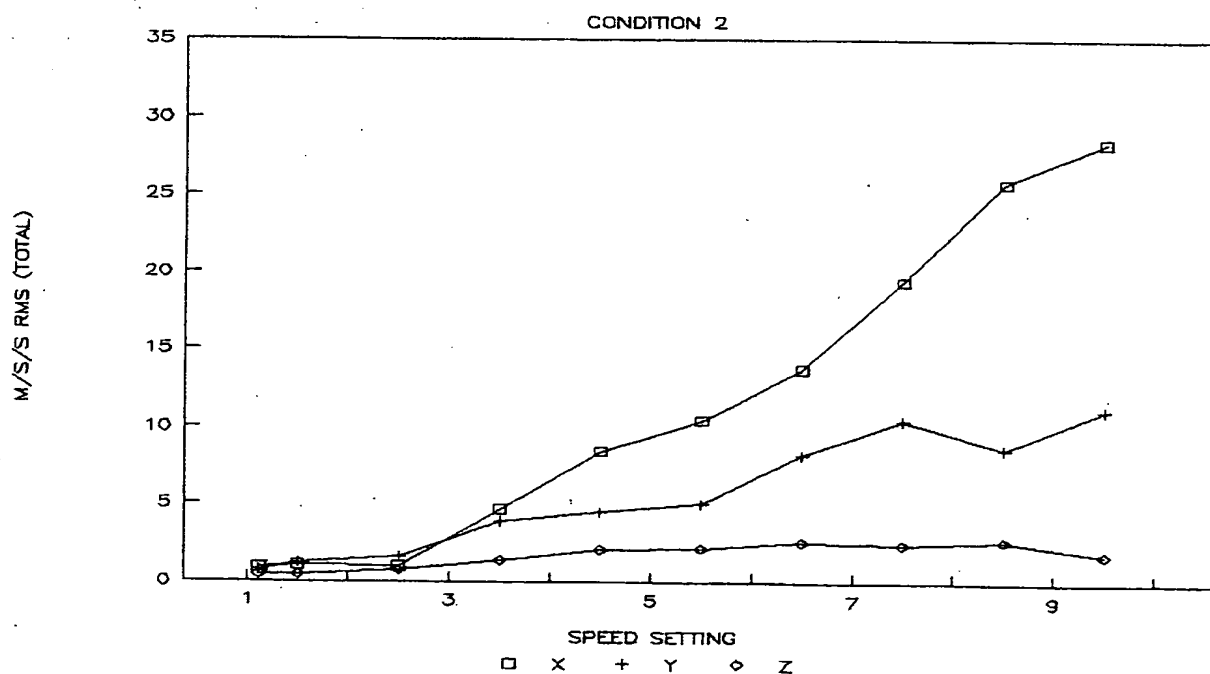


Figure 8b

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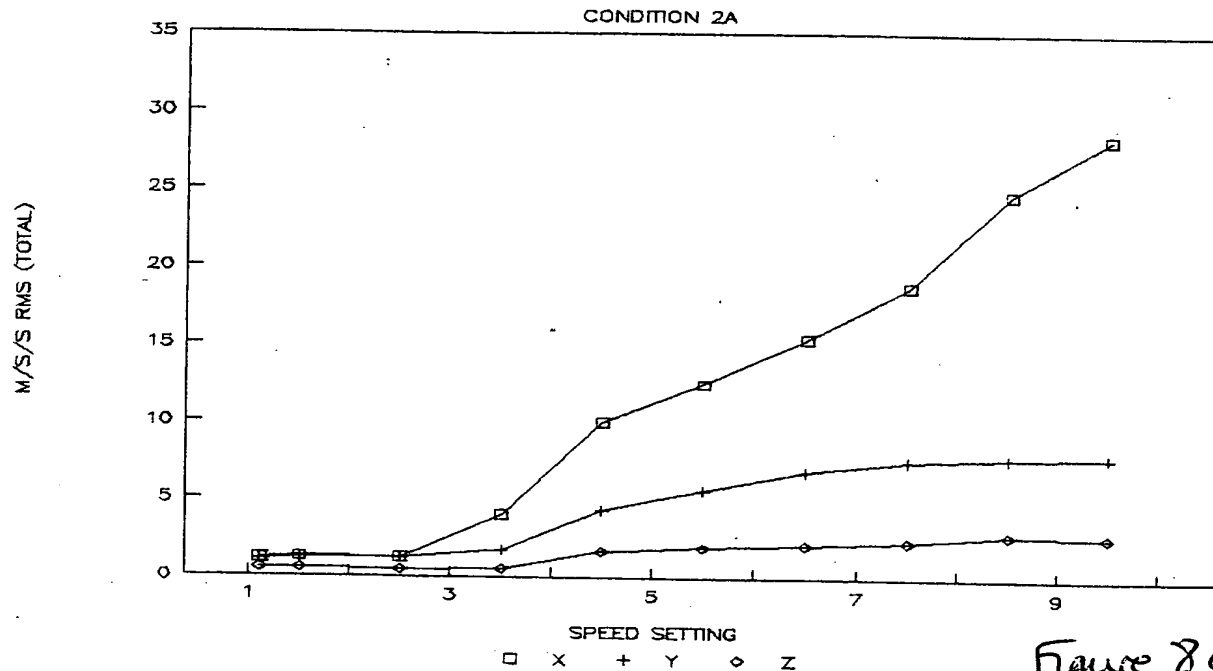


Figure 8c

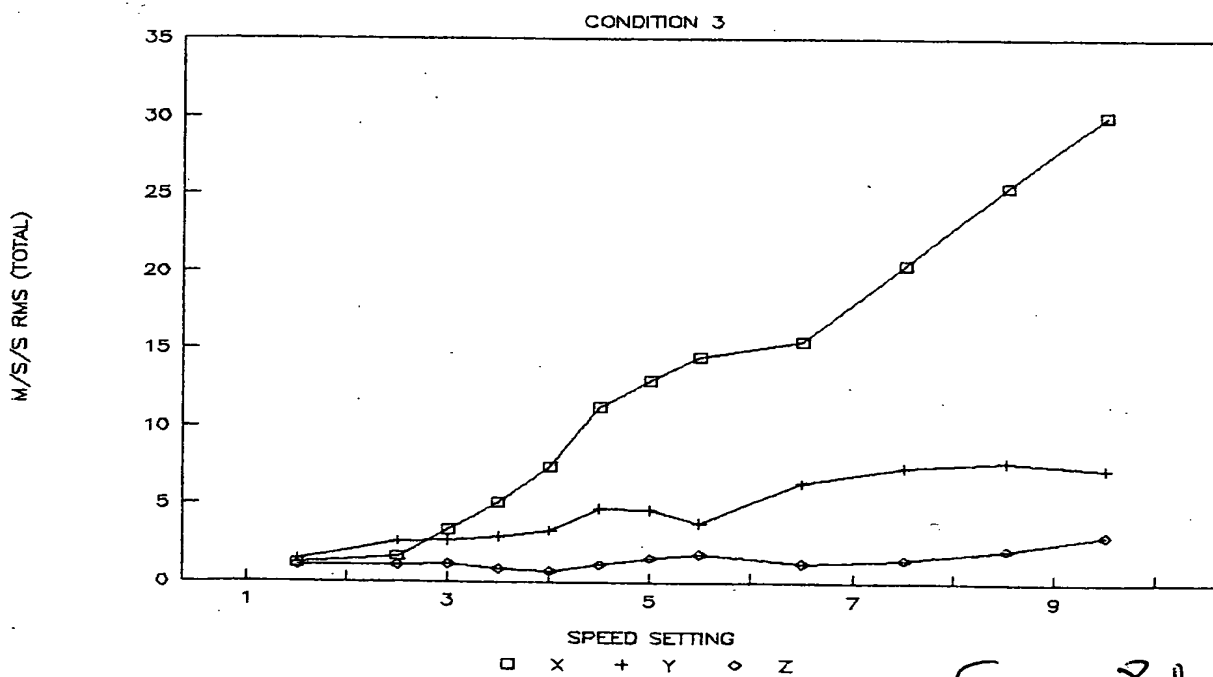


Figure 8d

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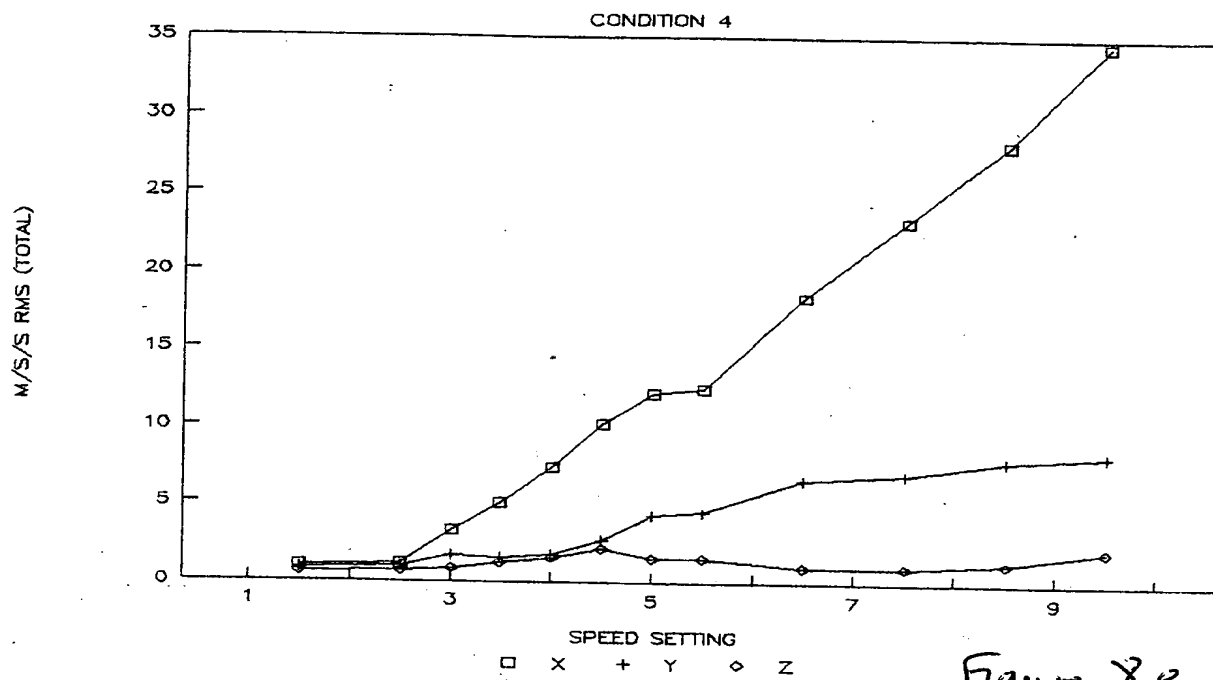


Figure 8e

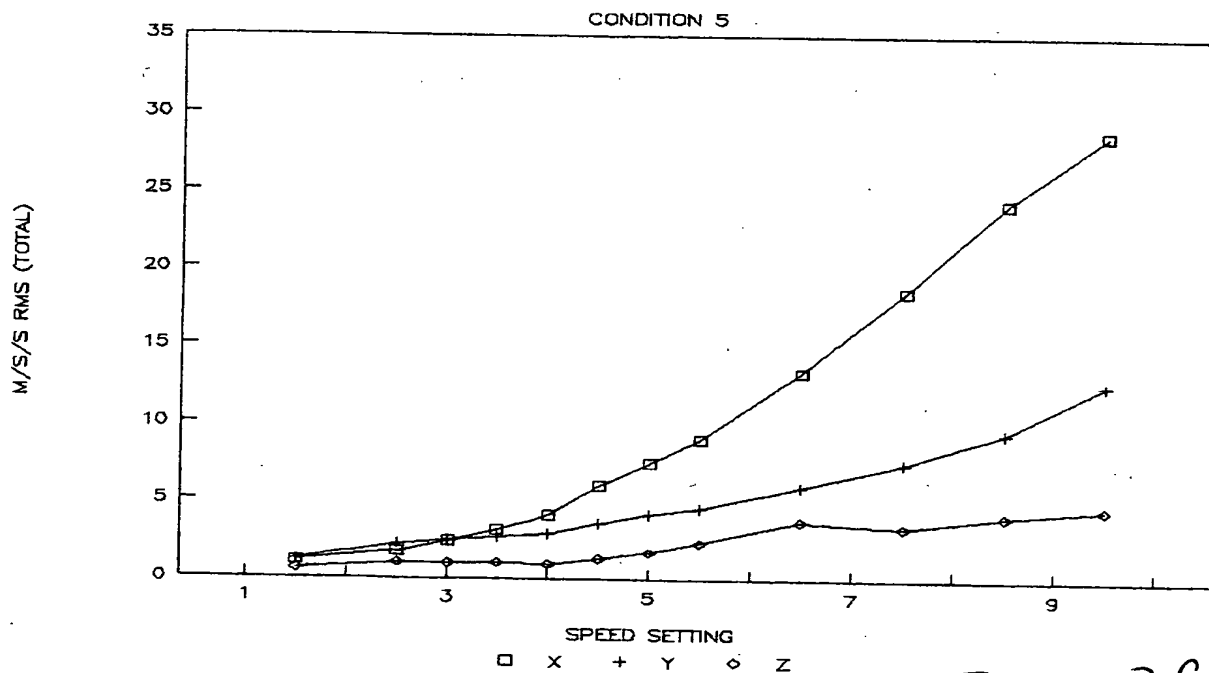


Figure 8f

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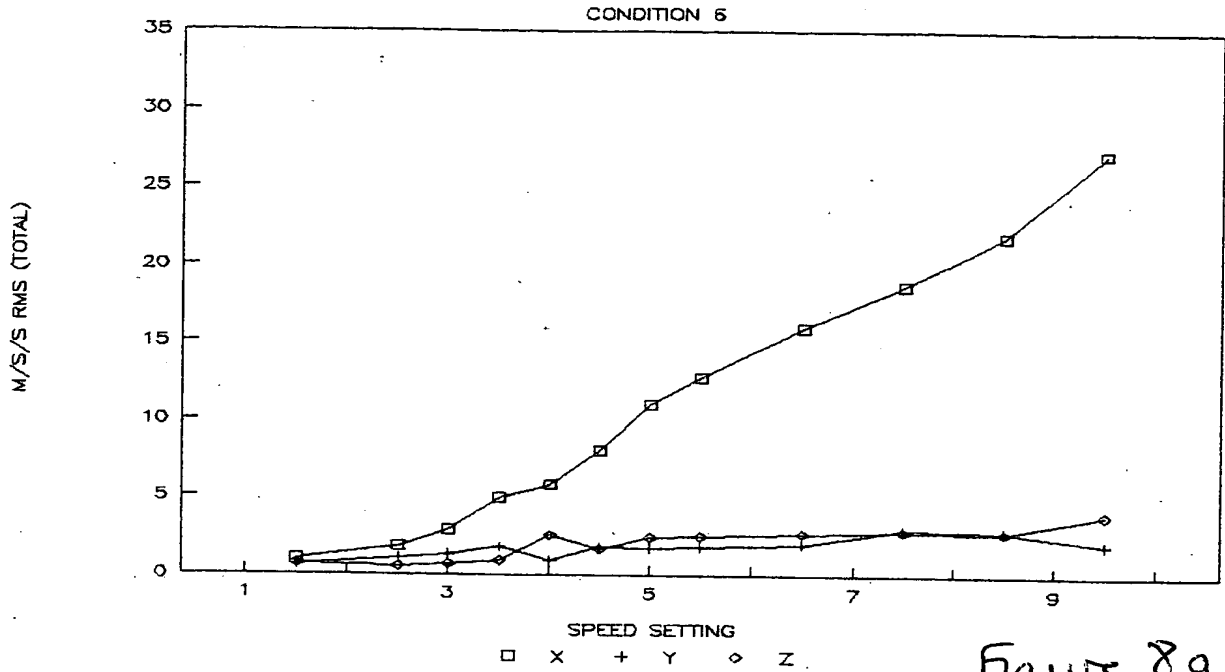


Figure 8g

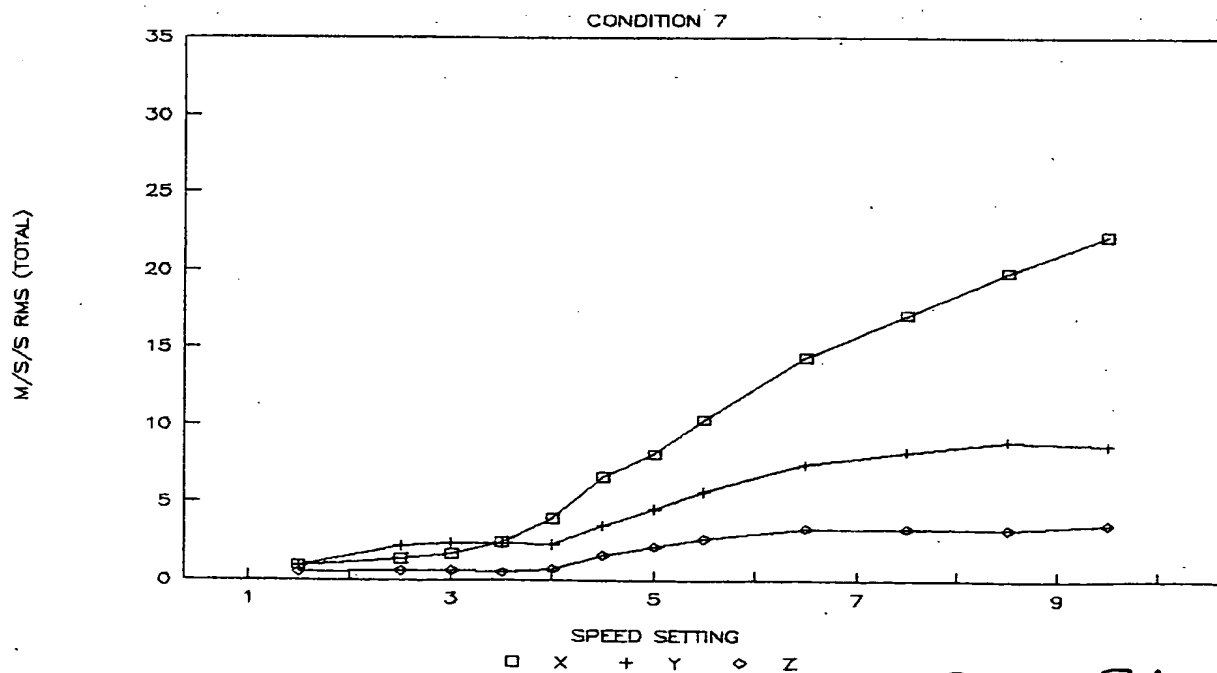


Figure 8h

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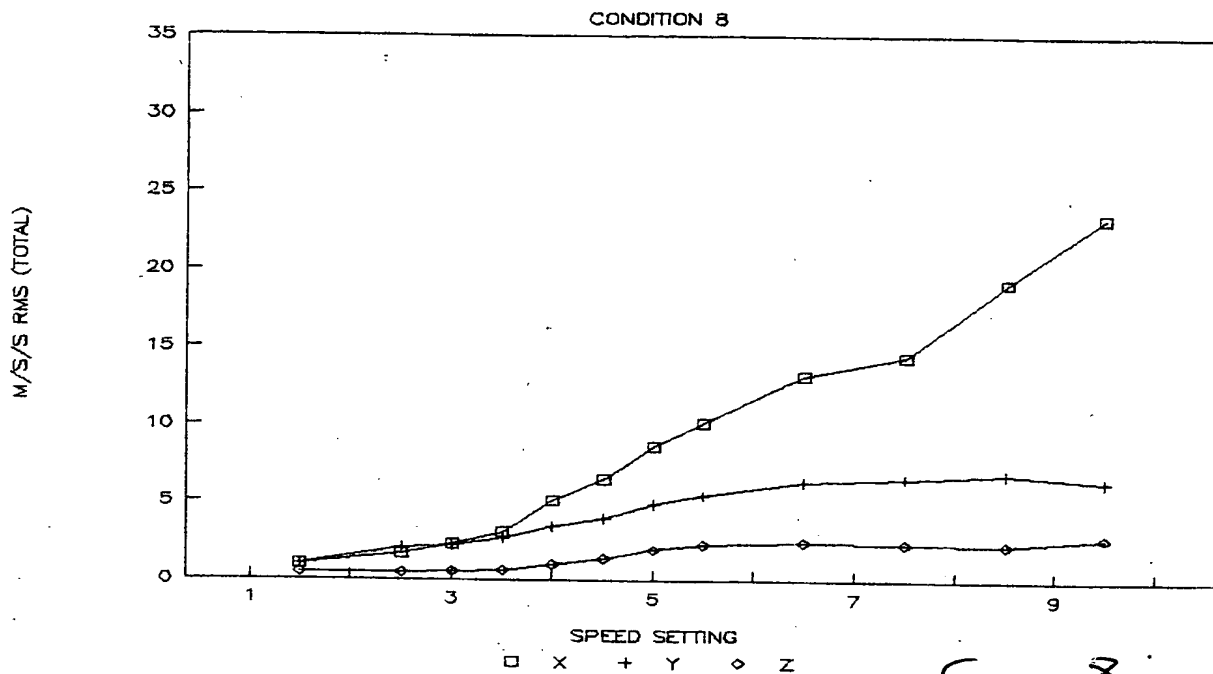


Figure 8i

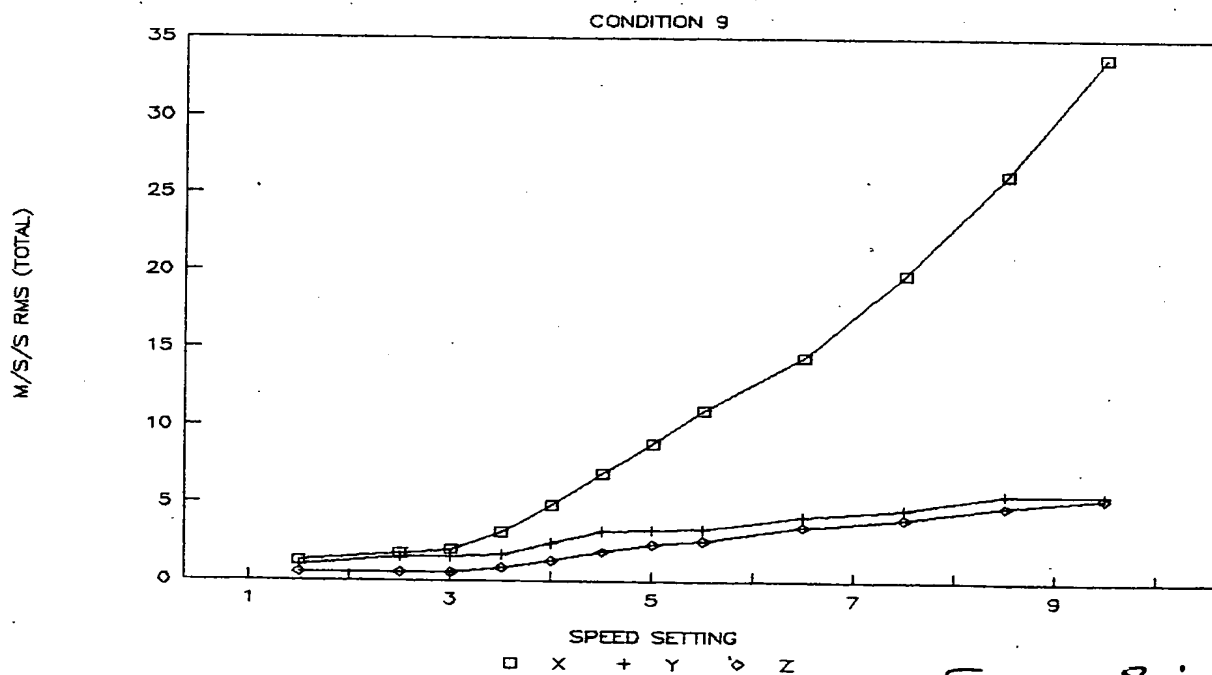


Figure 8j

4.1. Sample record - setting 4.5

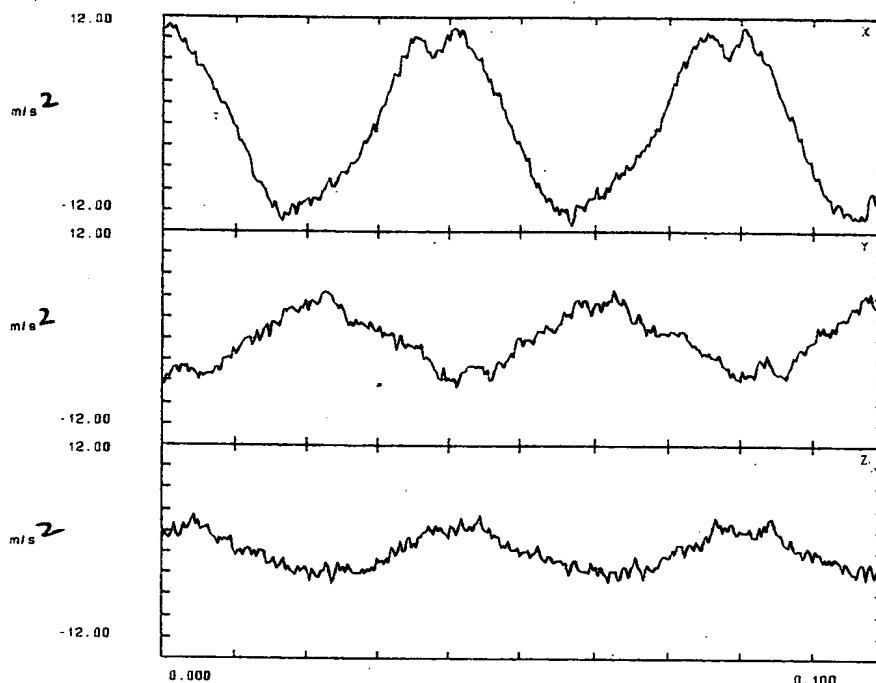


Figure 9a

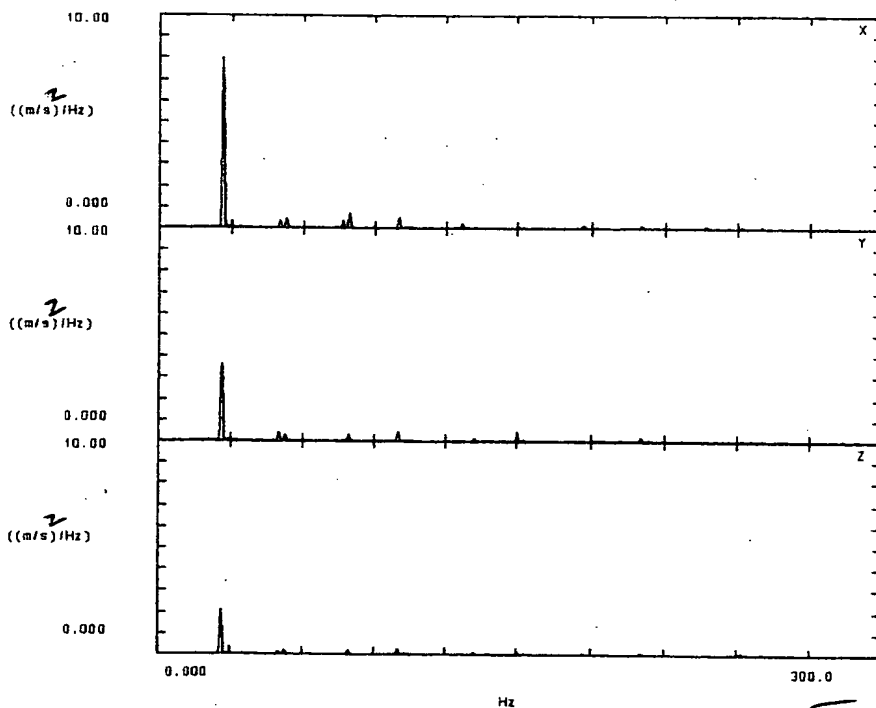


Figure 9b

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4.2. Sample record - setting 9.5

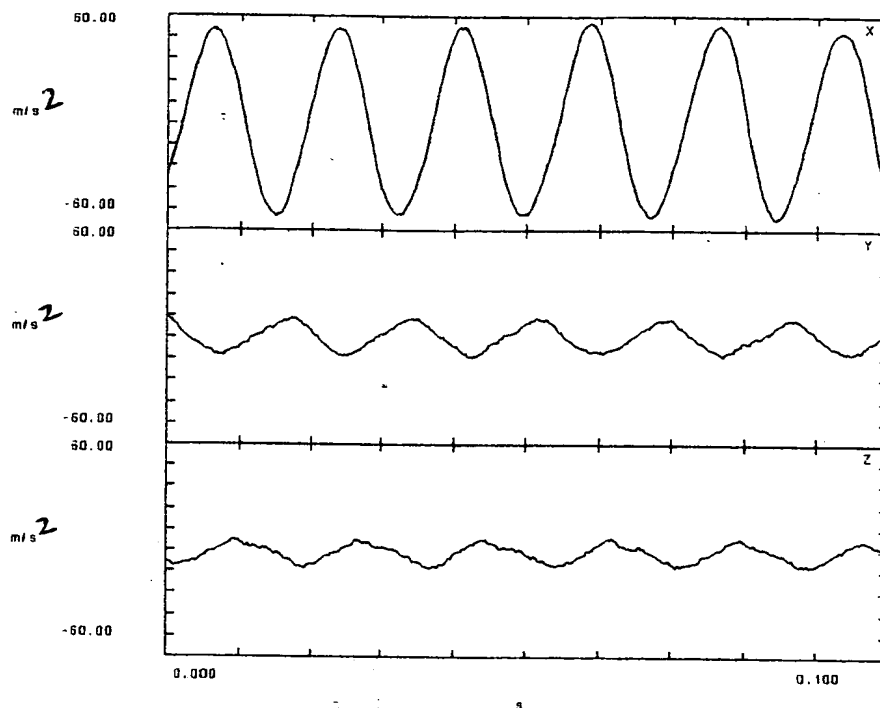


Figure 10a

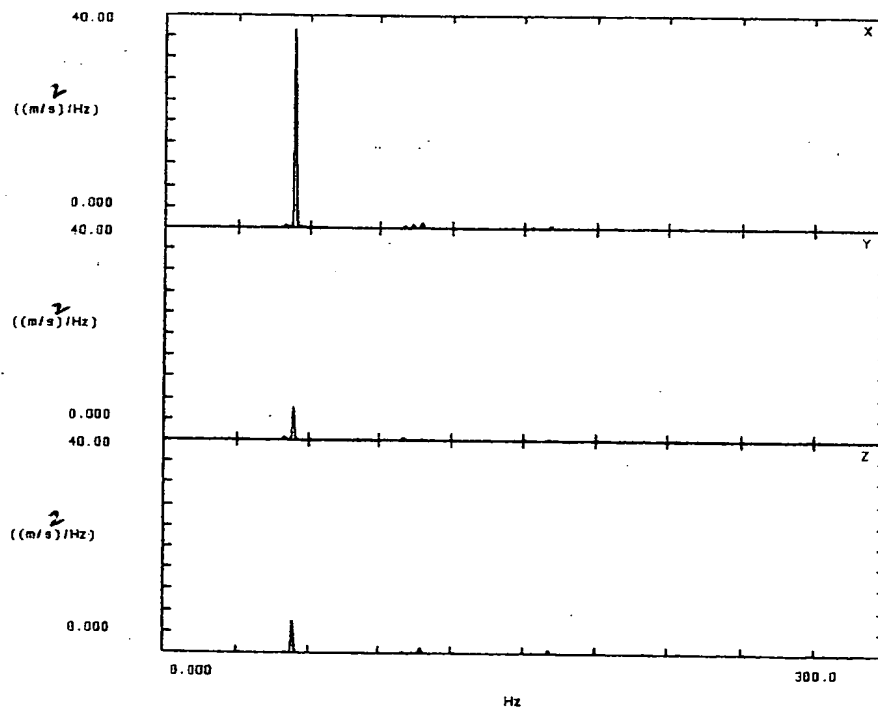


Figure 10b

3. Cycloidal tests - speed/frequency checks

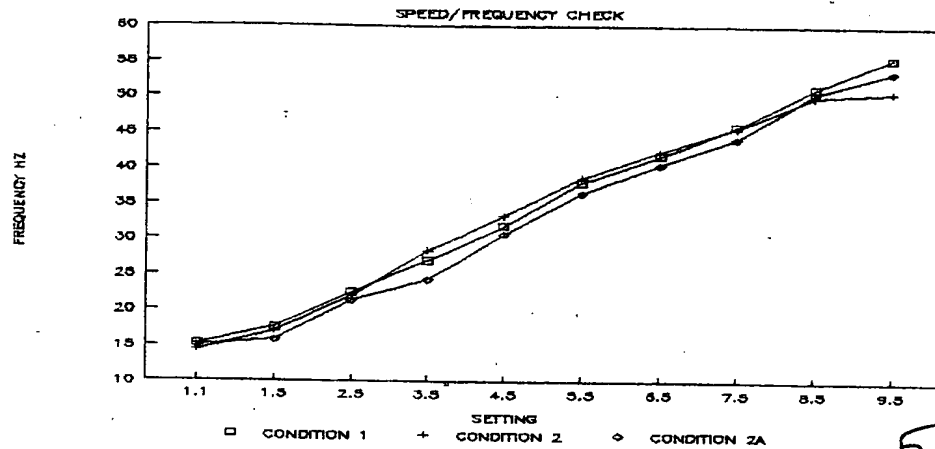


Figure 11a

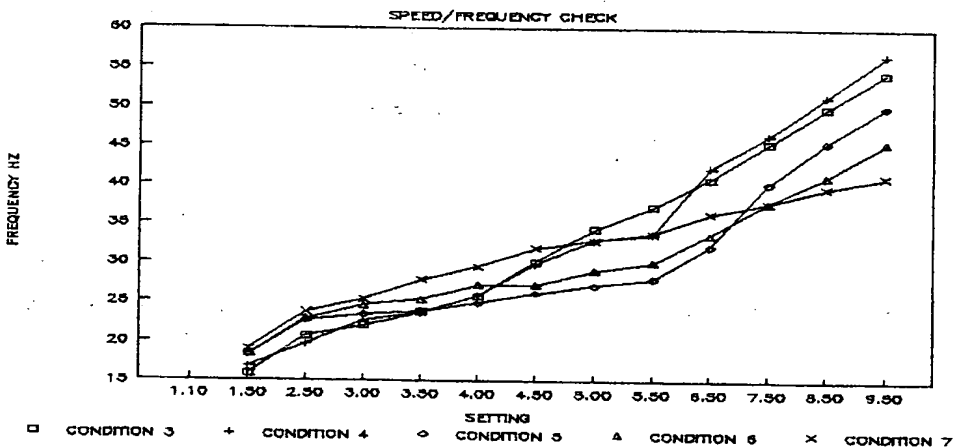


Figure 11b

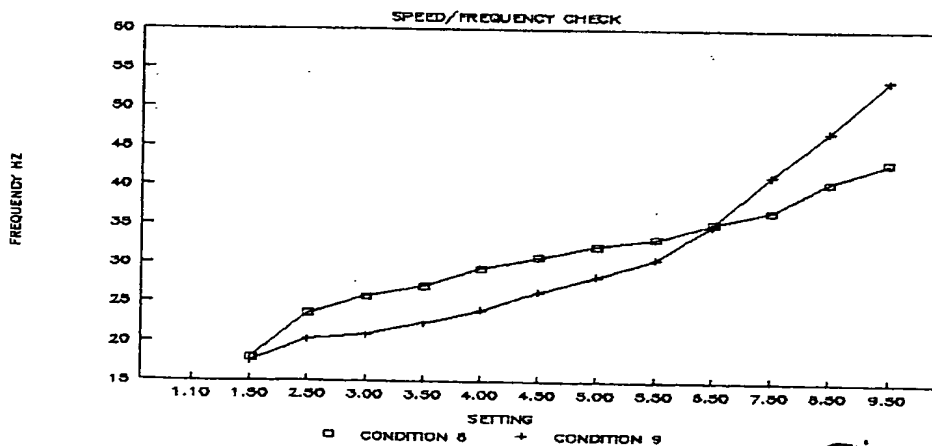
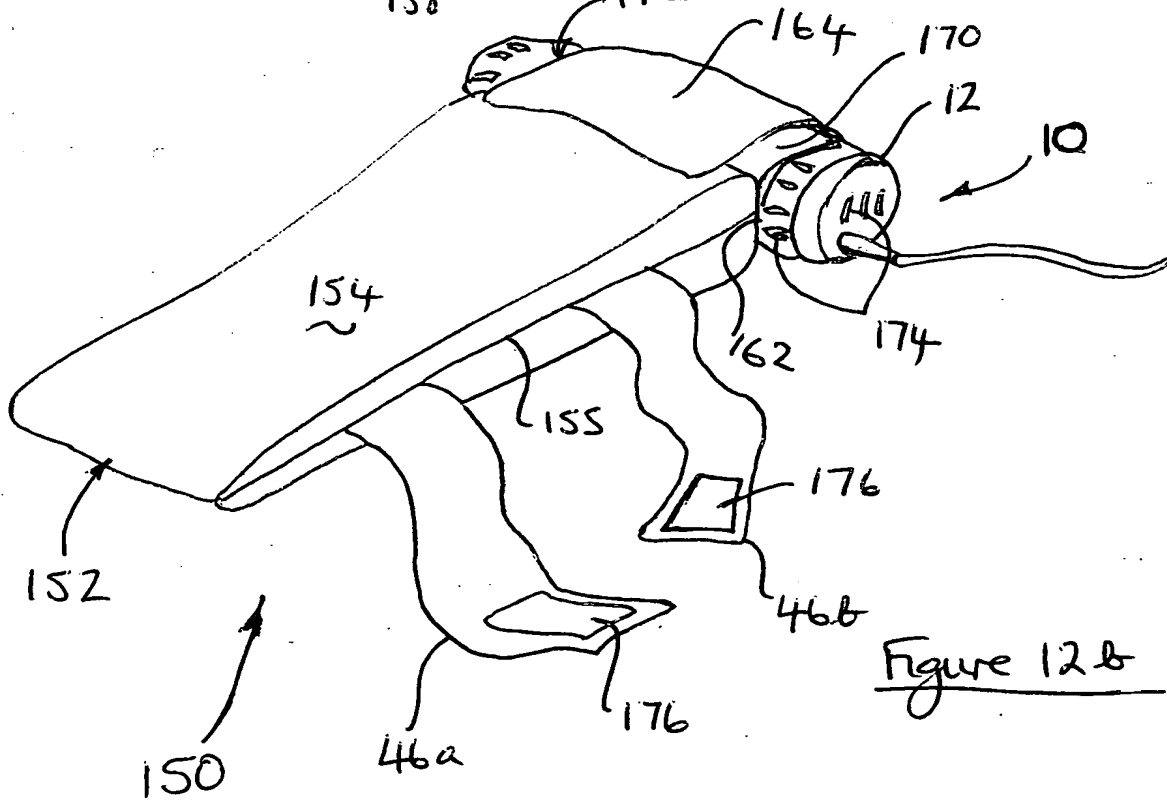
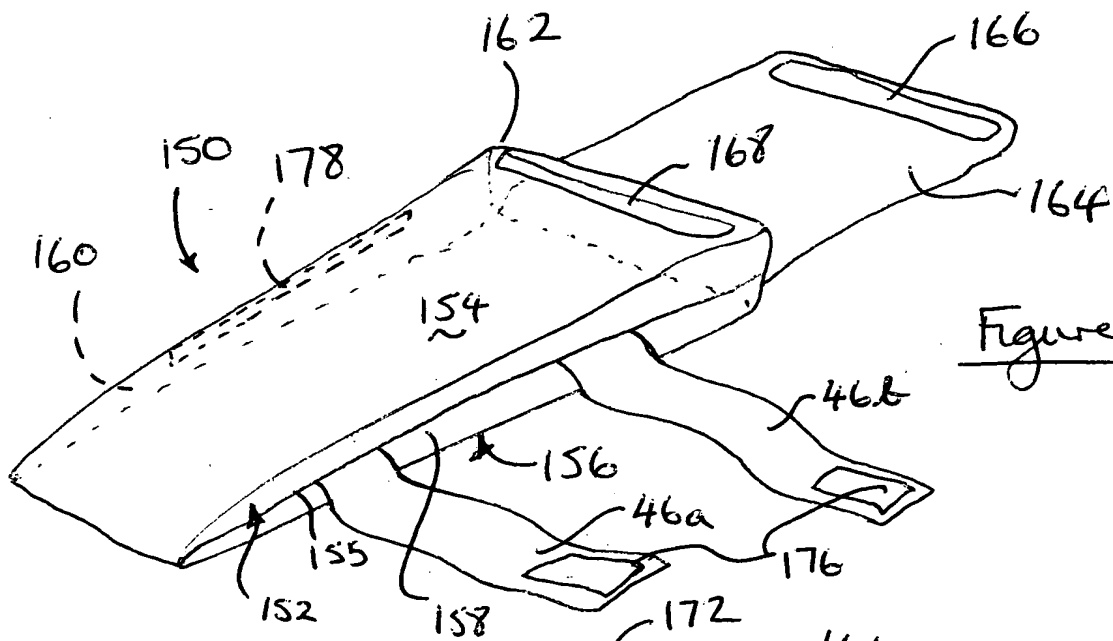


Figure 11c

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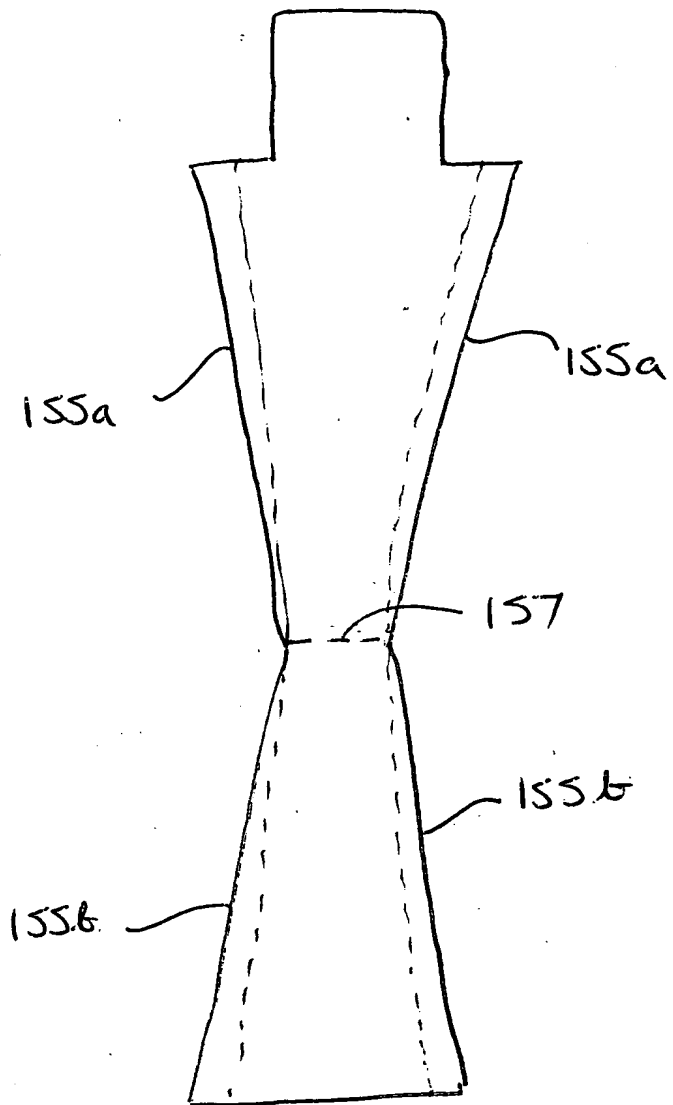


Figure 12c

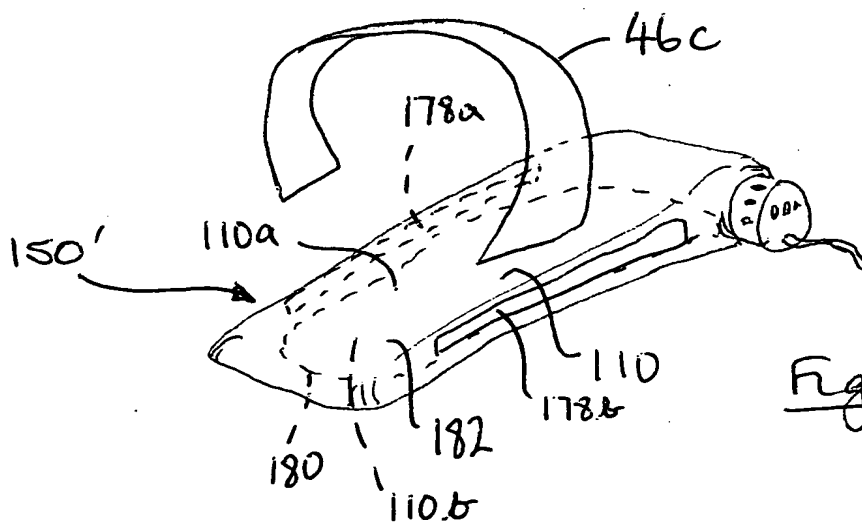


Figure 13